

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Loosmore et al.
U.S. Serial No.: 10/714,781
Filed : November 17, 2003
For : RECOMBINANT VACCINE AGAINST WEST NILE VIRUS
Examiner : Mary Mosher
Art Unit : 1648
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DECLARATION UNDER 37 C.F.R. § 1.132

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

I, Bob Nordgren, declare and state that:

1. I am Head of Global Biologics R&D at Merial Limited.
2. U.S. Application Serial No.10/714,781 ("the present application") is assigned to Merial Limited by virtue of an assignment recorded at the USPTO on October 8, 2004 at Reel 01588 and Frame 0238.
3. I understand that in making an obviousness determination, the Examiner may assess evidence related to secondary indicia of non-obviousness such as commercial success of the present invention. A demonstration of commercial success can lead to the assumption that, if the invention were obvious, then someone else would have previously brought it to market.
4. The instant claims of the present application (attached herein as Exhibit A) encompass Merial Limited's RECOMBITEK[®] Equine West Nile Virus (WNV) Vaccine ("the Merial Vaccine"). The Merial Vaccine comprises a recombinant canarypox virus that encodes and expresses *in vivo* the WNV polyprotein prM-M-E (see product specification, attached herein

as Exhibit B). Therefore, the evidence presented herein that demonstrates commercial success of the Merial Vaccine is commensurate in scope with the instant claims.

5. The Merial Vaccine was launched in 2004. At the time, the market for equine vaccines against WNV included Fort Dodge Animal Health's West Nile -- Innovator[®], which is a killed virus vaccine. While West Nile -- Innovator[®] had an exclusive presence in the market since August of 2001 (*see* Briggs, *The Horse*, March 2005, 3-7; attached herein as Exhibit C), the Merial WNV Vaccine quickly experienced commercial success as it enjoyed a 11 % share of the market during its full year (2004). Since then, the Merial Vaccine has commanded at least a 6 % share of the market each year (*see* Table 1).

Table 1. The Merial Vaccine's share of the market from 2004-2008.

Year	Share of the Market
2004	11 %
2005	8 %
2006	8 %
2007	6 %
2008	8 %

6. The number of WNV equine infections reported by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture decreased each year since 2003 (*see* Table 2). The Merial Vaccine was and is the only vaccine that has been demonstrated to protect against natural mosquito borne challenge. The Merial Vaccine also has been shown to protect against disease as well as infection.

Table 2. Number of reported cases of West Nile Virus infection in horses from 2003-2008 (http://www.aphis.usda.gov/vs/nahss/equine/wnv/wnv_distribution_maps.htm)

Year	Number of Cases	Decrease from Previous Year
2003	5181	--
2004	1406	- 72.9 %
2005	1088	- 22.6 %
2006	1086	- 0.1%
2007	468	- 56.9 %
2008	179	- 61.8 %

7. In my opinion, the success of the Merial Vaccine can be attributed to its design. The use of recombinant canarypox vectors provides a vehicle that can induce both humoral and cell-mediated immune responses against expressed transgene products (see Poulet et al. Vaccine, 2007, 25: 5606-5612; attached as Exhibit D). These advantages were realized in studies that showed that the recombinant canarypox encoding WNV polyprotein prM-M-E of the Merial Vaccine can provide complete protection in horses injected twice at 35-day interval, and challenged by virulent WNV via mosquito-borne infection (see specification of the present application, Example 25). The Merial Vaccine also protected horses vaccinated twice at 35-day interval, and challenged by virulent WNV via intrathecal administration (see Siger et al. Veterinary Therapy 2006, 7: 249-256; attached herein as Exhibit E). Furthermore, a single dose of the Merial Vaccine protected 8 out of 9 horses challenged by virulent WNV via mosquito-borne infection (see specification of the present application, Example 32; see also Siger et al. Am J Vet Res 2004, 65: 1459-1462, attached as Exhibit F).

8. In summary, the Merial Vaccine, encompassed by the instant claims of the present application, has experienced commercial success in protecting horses against WNV infection. This commercial success has been associated with a significant decrease in the number of WNV infections in horses since the Merial Vaccine launched into the market. Together, this information supports the argument that the Merial Vaccine encompassed by the instant claims is not obvious, as another would have brought a recombinant canarypox virus to market if it were an easy and non-inventive product to develop.

9. I declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application or any patent issued thereon.

Nov 9 '09

Date



Signature

Bob Nordgren

Printed Name